JUL 1 2 2001

K011291

510(k) Summary

Submitter's Name:	Exergen Corporation
Address:	51 Water Street Watertown, MA 02172
Phone:	(617) 923-9900 (800) 422-3006
Fax:	(617) 923-9911
Contact:	Gerald A. Clay
Date of Summary:	April 27,2001
Trade Name:	TemporalScanner Thermometer, formerly known as SensorTouch
Classification:	Thermometer, Clinical, Electronic Product Code: FLL Regulation No. 880.2910 Class: II Panel: 80 (General Hospital)
Predicate Device(s):	Exergen Surface Temperature Scanner (K 873010) (Exergen Predicate) Braun Thermoscan IRT 3020/3520 (K983295)(Braun Predicate)
Device Description:	The TemporalScanner is a hand held, battery operated device that measures the skin temperature of the skin over the temporal artery. Operation is based on measuring the natural thermal infrared radiation emitted from the surface of the skin over the temporal artery.
Intended Use:	The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.
Characteristics:	**Technological** The TemporalScanner Thermometer and the predicate devices are all used to measure the temperature of a human by means of a thermopile

infrared sensor transducer coupled with electronic signal amplification, conditioning, and display unit.

The Exergen Predicate employed solid-state electronic signal amplification which is technology similar to the electronic surface mount technology used by the TemporalScanner Thermometer and the Braun Predicate. The Braun Predicate's signal conditioning consists of making mathematical adjustments to display the familiar oral range. Similarly, the TemporalScanner Thermometer's signal conditioning consists of making mathematical adjustments to the temperature measured at the skin surface over the temporal artery to display the familiar rectal range. All display units are solid-state displays, with the Exergen Predicate using an LED display while the TemporalScanner Thermometer and the Braun Predicate employ an LCD display.

All of the devices meet ASTM E1965-98 *Standard for Infrared Thermometers for Intermittent Determination of Patient Temperature, to the extent that this standard applies to them.*

The primary difference between the TemporalScanner Thermometer and the Braun Predicate is that the Braun Predicate measures the temperature of the auditory canal and mathematically converts and displays a familiar oral temperature, while the TemporalScanner measures surface skin temperature over the temporal artery and mathematically converts and displays a familiar rectal temperature.

Summary of non-clinical Performance Testing:

Performance test	**Results**
Accuracy tests	Pass
Repeatability tests	Pass
$^{\circ}$F vs $^{\circ}$C tests	Pass
Variable voltage tests	Pass
Error messages tests	Pass
Display limits test	Pass
EMC tests	Pass
Current leakage test	Pass
DFU evaluation	Pass

Conclusion:	Since performance testing confirms conformance to the same standard as both predicate devices, we conclude the device is substantially equivalent to those devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Exergen Corporation
C/O Mr. William Hare
Associate
Fish and Richardson, PC
601 13th Street, NW
Washington, DC 20005

Re: K011291
Trade/Device Name: TemporalScanner Thermometer, SensorTouch
Regulation Number: 880.2910
Regulatory Class: II
Product Code: FLL
Dated: April 27, 2001
Received: April 27, 2001

Dear Mr. Hare:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011291
Device Name: TemporalScanner Thermometer

Indications For Use: The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

90428.W11

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
(510(k) Number K011291